

**Notice of Allowability**

Application No.

09/593,173

Examiner

Evelyn Huang

Applicant(s)

GUARNA ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to response filed on 11-1-2004.
2. ☒ The allowed claim(s) is/are 1-3,10 and 27-29.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____  |

***EXAMINER'S AMENDMENT***

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Costigan on 3-10-2005. During the interview, the examiner suggested the following to place the application in conditions for allowance: (i) amending claims 1, 28, 29 to better define the claims; (ii) inserting 'CN, COOR, CONRR', C(=O)R' in the definitions of R1-R4, R6 in claim 1 to provide antecedent basis for these groups in claim 2, and (iii) amending claim 27 by deleting prostatic cancer and prostatic hypertrophy to be commensurate in scope with that of the objective enablement.

The application has been amended as follows:

- a. Claim 1,
  - Definition of X, replace CONNR' with – CONRR' --.
  - Definition of R1, R2, R3, R4, R6, line 2, after 'H', insert –CN, COOR, CONRR', C(=O)R, --.
  - Definition of n, replace 'comprised between 1 and 4' with – of 1 to 4 --.
  - Replace 'and their pharmaceutically acceptable salts' with – or a pharmaceutical acceptable salt thereof --.
- b. Claim 27,
  - Line 1, replace 'inhibition' with – treatment --
  - Line 2, replace 'caused by 5 $\alpha$  reductase I and/or 5 $\alpha$  reductase II' with –related to 5 $\alpha$  reductase --.
  - Line 5, delete 'prostatic cancer and prostatic hypertrophy'.
- c. Claim 28,

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- Definition of X , replace CONNR' with – CONRR' --.
- Definition of n, replace 'comprised between 1 and 4' with – of 1 to 4 --.
- Replace 'and their pharmaceutically acceptable salts' with – or a pharmaceutical acceptable salt thereof --.

d. Claim 29,

- Definition of X , replace CONNR' with – CONRR' --.
- Definition of n, replace 'comprised between 1 and 4' with – of 1 to 4 --.
- Replace 'and their pharmaceutically acceptable salts' with – or a pharmaceutical acceptable salt thereof --.

### ***REASONS FOR ALLOWANCE***

2. The following is an examiner's statement of reasons for allowance:

Claims 1-3, 10, 27-29 are allowed.

The 112 first paragraph rejection is withdrawn in view of the amendment limiting the method to treatment of acne, baldness in men, or hirsutism in women, which find support on page 2 of the specification.

The 112 second paragraph rejection is withdrawn in view of the amendment and Applicant's Remarks.

The 102(b) rejection over Acheson is withdrawn upon reconsideration in view of Applicant's Remarks. The prior art compound is a benzoquinolizine, whereas the instant is a partially or fully reduced benzoquinolizine.

The timely filed terminal disclaimer has obviated the obviousness type double patenting rejection over 6514912 and the obviousness type double patenting rejection over 6303622.

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The 103 rejection over WO 97/29107 in view of Guarna (J. Med. Chem. 1997, Vol. 40, page 1117) and Strandtmann is withdrawn upon reconsideration in view of the amendment and Applicant's Remarks. WO 97/29107 teaches a 5-alpha reductase inhibiting benzoquinolize compound, whereas the instant is a partially or fully reduced benzoquinolizine. Guarna only teaches a 5-alpha reductase inhibiting azasteroid, and Strandtmann only teaches the synthesis of benzoquinolizine and dibenzoquinolizine. Absent is the motivation to modify the benzoquinolizine of WO 97/29107 to arrive at the instant invention.

The 103 rejection over WO 99/05913 in view of Guarna (J. Med. Chem. 1997, Vol. 40, page 1117) and Strandtmann is withdrawn upon reconsideration in view of the amendment and Applicant's Remarks. WO 99/05913 is not available as prior art for the following reasons: it has the same inventive entity as the instant, and it is published on 2-11-1999, which is after the instant effective filing date of 12-21-1998 (filing date of PCT/EP98/08582). The compounds in the instant claims, the composition and method of use thereof are described in PCT/EP98/08582, filed on 12-21-1998.

The 103 rejection over EP 926148 in view of Guarna (J. Med. Chem. 1997, Vol. 40, page 1117) and Strandtmann is withdrawn upon reconsideration in view of the amendment and Applicant's Remarks. EP 926148 is not available as prior art for the following reasons: it has the same inventive entity as the instant, and it is published on 6-30-1999, which is after the instant effective filing date of 12-21-1998 (filing date of PCT/EP98/08582). The compounds in the instant claims, the composition and method of use thereof are described in PCT/EP98/08582, filed on 12-21-1998.

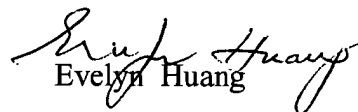
3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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